AUG 1 8 2010

510(k) Summary

Sponsor:	Zimmer GmbH Sulzerallee 8, P.O. Box 8404 Winterthur, Switzerland
Contact Person:	Tim Crabtree Senior Regulatory Affairs Specialist Telephone: 952.857.5631
Date:	June 14, 2010
Trade Name:	Zimmer® DTO® Pin Press
Common Name:	Spinal System Instruments
Classification Name:	Pedicle screw spinal system
Reference:	21 CFR 888.3070
Predicate Device:	*Zimmer DTO Hand*-Press, K071879
Performance Testing:	It has been determined that the proposed *Zimmer DTO* Pin Press is substantially equivalent the predicate Zimmer DTO Hand Press. Based on the results following tests: • Durability and fatigue • Interconnection strength • Pull-out strength
Device Description:	The *Zimmer DTO* Pin press has been designed to be part of the *Zimmer DTO* Instruments. The *Zimmer DTO* Implant is provided partially assembled, in that the cord is placed in the connecting part and fixed with a needle during the manufacturing process; the mechanical integrity of the cord/rod connection is achieved immediately prior to implantation by fully inserting a pin to compress the cord with an intra-operative instrument, this step is performed with the *Zimmer DTO* Pin press.
Indications:	When used as a pedicle screw fixation system in skeletally mature patients, the *Dynesys Spinal System* is intended to provide immobilization and

stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment and failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the Dynesys system is indicated for use in patients:

- Who are receiving fusions with autogenous graft only;
- Who are having the device fixed or attached to the lumbar or sacral spine;
- Who are having the device removed after the development of a solid fusion mass.

When the *Dynesys Spinal System* and the *OPTIMA ZS Spinal System* are used on contiguous levels, they must be used with the *Zimmer DTO* Implant, rod-cord combination implant, and the U & I Corporation *OPTIMA ZS Transition Screw*. The indications for use for each level is as specified for each system.

Substantial Equivalence:

Based on testing it has been determined that the *Zimmer DTO* Pin press is substantially equivalent to the predicate *Zimmer* DTO Hand-press. The proposed Pin Press has the same intended use, materials, and technology as the *Zimmer DTO* Hand Press.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Zimmer Spine, Inc.
% Mr. Tim Crabtree
Senior Regulatory Affairs Specialist
7375 Bush Lake Road
Minneapolis, Minnesota 55439-2027

AUG 1 8 2010

Re: K101704
Trade/Device Name: Zimmer® DTO® Pin Press Instrument
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: NQP
Dated: July 19, 2010
Received: July 20, 2010

Dear Mr. Crabtree:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may; therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

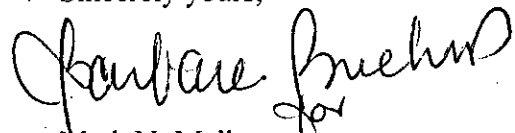
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101704

SECTION V: Indications for Use Statement

510(k) Number (if known): K101704

Device Name: *Zimmer DTO* System/Pin Press

Indications for Use:

When used as a pedicle screw fixation system in skeletally mature patients, the *Dynesys Spinal System* is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment and failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the Dynesys system is indicated for use in patients:

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101704